REMARKS

Claims 1, 7-9, 40, and 42-50 are pending in the instant application. Claims 44, 45, and 50 have been amended to clarify what Applicant regards as the invention. Specifically, claims 44 and 45 have been amended so that the dependent claim 45 further limits claim 44. Claim 45 has also been amended to depend from both claims 43 and 44. Claim 50 has been amended to depend from claims 1, 7, 8, and 9. Applicant believes that no new matter is introduced by these amendments. Accordingly, claims 1, 7-9, 40, and 42-50 will be pending upon entry of this amendment.

1. THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR LACK OF WRITTEN DESCRIPTION SHOULD BE WITHDRAWN

The Examiner has maintained the rejection of claims 1, 7-9, 40, and 42-50 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The rejection is based on the Examiner's position that the specification lacks adequate written description to support the claim term, "an antigenic molecule which displays the antigenicity of an antigen." Specifically, the Examiner alleged at page 6 of the November 17, 2004 Office Action ("the November 2004 Office Action") that "neither the claims nor the specification teach any identifiable characteristics that are associated with these 'antigenic molecules which display the antigenicity' of a tumor or infectious agent" and that a representative number of species is not provided that would support the full scope of the genus of antigenic molecules claimed.

In response, Applicant respectfully maintains that the specification satisfies the written description requirement of 35 U.S.C. §112, first paragraph, with respect to the claimed antigenic molecules because numerous examples of such molecules were known in the art, making their recitation in Applicant's disclosure unnecessary. It is a well settled rule that a patent need not describe that which is well known in the art, see *e.g.*, *Capon v. Dudas* (No. 03-1480, Fed. Cir. August 12, 2005, at page 14)(stating that precedents do not "require a re-description of what was already known" to satisfy the written description requirement).

In the November 2004 Office Action the Examiner acknowledged the principle that a patent need not describe that which is well known in the art when he conceded at page 6 that tumor antigens and infectious agents (presumably intending to include antigens of infectious agents) are known in the art and therefore need not be described in detail in the specification. Accordingly, the Examiner rests the present rejection on the grounds that, unlike the antigens themselves, the *determinants of antigenicity* have not

been sufficiently disclosed in the specification and are not conventionally known in the art (see page 6 of the November 2004 Office Action). Thus, the Examiner states that "specific, not general guidance is required" to support the claims which recite antigenic molecules which display the antigenicity of an antigen (see the November 2004 Office Action at page 7 and the current Office Action at page 5).

First, Applicant points out that the basis for the Examiner's rejection does not apply to claims 45 and 50, which recite an antigenic molecule that is an antigen of an infectious agent (claim 45) or a tumor-specific or tumor-associated antigen (claim 50). As noted above, the Examiner has conceded that such antigens were well known in the art at the time of filing. Accordingly, the rejection as it applies to claims 45 and 50 is improper.

With respect to the remaining claims, Applicant maintains that, contrary to the Examiner's assertion, molecules which display the antigenicity of a tumor-specific or tumor-associated antigen or an antigen of an infectious agent were also well-known in the art at the time of filing the subject application. Such molecules are molecules which contain an epitope of a tumor-specific or tumor-associated antigen or an epitope of an antigen of an infectious agent. The prior art contains numerous specific examples of such molecules as well as routine methods for predicting such epitopes. The prior art also describes routine methods for testing whether a molecule displays the antigenicity of an antigen.

In support of his position, Applicant refers the Examiner to three exemplary prior art references submitted in Applicant's Supplemental Information Disclosure Statement filed herewith: Rammensee et al. (1995) *Immunogenetics* 41:178-228 ("Rammensee")(reference "**EN**"); Lovett et al. (1993) *J. Virology* 76:5849-5858 ("Lovett")(reference **"EP");** and Thomson et al. (1996) *J. Immunol.* 157:822-826 ("Thomson")(reference **"EQ").** Applicant submits that these three references disclose numerous examples of molecules that display the antigenicity of a tumor-specific or tumor-associated antigen or an antigen of an infectious agent and that were known in the art prior to the filing of the subject application.

Rammensee provides tables containing numerous specific examples of amino acid sequences that are recognized in the art as T-cell epitopes. Many of the epitopes described by Rammensee are also disclosed to be epitopes of particular tumor-specific or tumor-associated antigens or epitopes of particular antigens of infectious agents. For example, Table 2 beginning at page 192 provides approximately 31 specific T-cell epitopes, many of which are of tumor-specific or tumor-associated antigens (*e.g.*, the melanoma associated antigens MAGE-1 and MAGE-2, tyrosinase, and Mart) or of antigens of infectious

agents (*e.g.*, influenza, hepatitis, and human immunodeficiency virus proteins). Additional T cell epitopes of tumor specific or tumor-associated antigens or antigens of infectious agents are listed in Table 2 *et seq*. See also the numerous references cited by Rammensee. Thus, Rammensee provides numerous specific examples of molecules which display the antigenicity of a tumor-specific or tumor-associated antigen or an antigen of an infectious agent. Additional examples of such molecules can be found in a database of MHC ligands that became available to the public in 1999 (see *Immunogenetics* 1999 50:213-219, attached hereto as reference **"EO"** of Applicants' Supplemental IDS).[1] The database is arranged similarly to the tables in the Rammensee reference so that known epitopes are listed below the examples of MHC ligands and arranged by species and MHC class. Molecules comprising such epitopes can be readily constructed and recognized by the skilled artisan.

Lovett describes several molecules, each comprising one or more T-cell epitopes of the rubella virus capsid protein (see e.g., page 5854, col. 1, paragraphs 2 and 3, and Table 3). Lovett further describes an assay for testing the antigenicity of these molecules (see pages 5850-5851, describing the "CTL assay" and pages 5854-5855, describing its use to test the antigenicity of the molecules in Table 3). Thomson discloses nine molecules, each comprising a T cell epitope of an antigen of an infectious agent (see Table 1, page 823), as well as a tenth molecule containing multiple different T cell epitopes of different antigens of infectious agents (see Figure 1, page 823). Thomson further describes an effector cytotoxic T cell assay for testing the antigenicity of the molecule containing multiple epitopes (see page 823, col. 2 to page 824, col. 2). Other immunoassays that can be used are commonly known in the art.

In summary, Applicant has presented evidence that the prior art contains numerous specific examples of molecules which display the antigenicity of a tumor-specific or tumor-associated antigen or an antigen of an infectious agent, as well as assays for testing whether a molecule displays the antigenicity of an antigen. Such molecules are commonly known in the art. Accordingly, the Examiner's continued rejection of the claims for the failure of Applicant's specification to recite specific examples of such molecules is improper under the well settled rule, recently reaffirmed by the Federal Circuit in *Capon*, that Applicant's specification need not describe that which is already known in the art.

In *Capon*, the inventions were directed to chimeric genes formed from combinations of known DNA segments. The Board of Patent Appeals and Interferences ("the Board") rejected Applicant's claims for lack of written description because the specifications

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[1] This database is currently available at http://www.syfpeithi.de/ (last visited September 16, 2005).

at issue did not include the complete nucleotide sequence of at least one chimeric gene exemplary of the claimed genus. See *Capon* at page 11. The Federal Circuit reversed, explaining that, because the invention does not concern the discovery of gene function or structure, and rather concerns novel chimeric genes prepared from DNA segments of known structure and function, the specification need not recite specific sequences in order to satisfy the written description requirement. *Id.* at page 15. Like the claims to the chimeric genes at issue in *Capon*, the subject claims are directed to new compositions of matter comprising molecules known in the art, *i.e.*, an alpha (2) macroglobulin polypeptide and an antigenic molecule that displays the antigenicity of an antigen.

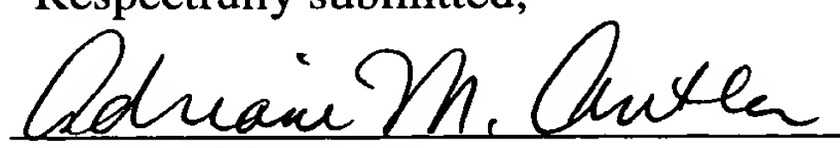
Applicant submits that his specification need not recite the sequences of specific antigenic molecules that display the antigenicity of an antigen because, like the DNA segments comprising the chimeric genes in *Capon*, such molecules were known in the art and their structure and function is not the subject of the claimed invention. Accordingly, Applicant maintains that claims 1, 7-9, 40, and 42-50 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, and respectfully request that the Examiner withdraw his rejection on this basis.

CONCLUSION

Entry of the foregoing amendment and remarks into the record of the above-identified application is respectfully requested. Applicant submits that the remarks and amendments made herein now place the claims in condition for allowance. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Date: December 12, 2005

Respectfully submitted,



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